European Medicines Agency

Doc. Ref. EMEA/610520/2009
P/191/2009

**EUROPEAN MEDICINES AGENCY DECISION**

**of 2 October 2009**

**on the acceptance of a modification of an agreed Paediatric Investigation Plan for alanine, arginine, aspartic acid, cysteine/cystine, glutamic acid, glycine, histidine, isoleucine, leucine, lysine monohydrate, methionine, ornithine hydrochloride, phenylalanine, proline, serine, taurine, threonine, tryptophan, tyrosine, valine, sodium chloride, potassium acetate, magnesium acetate, tetrahydrate, calcium chloride, sodium glycerophosphate, glucose, olive oil refined, soya-bean oil refined (EMEA-000112-PIP01-07-M01) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended**

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

*DISCLAIMER: This Decision does not entitle to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006, as amended.*

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THE EUROPEAN MEDICINES AGENCY,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use as amended and amending Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004[1],

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[2],

Having regard to the decision P/86/2008 of the European Medicines Agency on 14 October 2008,

Having regard to the application submitted by Baxter World Trade SA/NV on 7 August 2009 under Article 22 of Regulation (EC) No 1901/2006 as amended proposing changes to the agreed Paediatric Investigation Plan,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 18 September 2009, in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended,

Having regard to Article 25 of Regulation (EC) No 1901/2006 as amended,

WHEREAS:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the acceptance of changes to an agreed Paediatric Investigation Plan,

(2) It is therefore appropriate to adopt a Decision on the acceptance of changes to an agreed Paediatric Investigation Plan.

[1] OJ L 378, 27.12.2006, p.1
[2] OJ L 136, 30.4.2004, p. 1

HAS ADOPTED THIS DECISION:

*Article 1*

Changes to the agreed Paediatric Investigation Plan for alanine, arginine, aspartic acid, cysteine/cystine, glutamic acid, glycine, histidine, isoleucine, leucine, lysine monohydrate, methionine, ornithine hydrochloride, phenylalanine, proline, serine, taurine, threonine, tryptophan, tyrosine, valine, sodium chloride, potassium acetate, magnesium acetate, tetrahydrate, calcium chloride, sodium glycerophosphate, glucose, olive oil refined, soya-bean oil refined, solution for infusion, intravenous use, the details of which are set out in the Opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, are hereby accepted.

*Article 2*

This decision, that supersedes previous decision of the European Medicines Agency P/86/2008, is addressed to Baxter World Trade SA/NV, Boulevard de la Plaine 5, 1050 Brussels, Belgium.

Done at London, 2 October 2009

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

# OPINION OF THE PAEDIATRIC COMMITTEE ON THE ACCEPTANCE OF A MODIFICATION OF AN AGREED PAEDIATRIC INVESTIGATION PLAN

## Scope of the application

Active substance(s):
Alanine, arginine, aspartic acid, cysteine/cystine, glutamic acid, glycine, histidine, isoleucine, leucine, lysine monohydrate, methionine, ornithine hydrochloride, phenylalanine, proline, serine, taurine, threonine, tryptophan, tyrosine, valine; sodium chloride, potassium acetate, magnesium acetate, tetrahydrate, calcium chloride, sodium glycerophosphate, glucose, olive oil refined, soya-bean oil refined.

Condition(s):
Parenteral nutrition

Pharmaceutical form(s):
Solution for infusion

Route(s) of administration:
Intravenous use

Name/corporate name of the PIP applicant:
Baxter World Trade SA/NV

## Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Baxter World Trade SA/NV submitted to the EMEA on 7 August 2009 an application for modification of the agreed paediatric investigation plan as set out in the EMEA decision P/86/2008 of 14 October 2008. The application for modification proposed changes.

The procedure started on 20 August 2009.

## Scope of the modification

The applicant proposed modifications to the agreed PIP to clarify and revise some of the agreed measures and timelines.

**Opinion**

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

- to agree to the changes proposed by the applicant regarding the measures and the timelines of the paediatric investigation plan,

The Icelandic and the Norwegian Paediatric Committee members agree with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the paediatric investigation plan are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the Agency, together with its annex(es) and appendix.

London, 18 September 2009

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

(Signature on file)

## ANNEX I

## THE MEASURES AND TIMELINES OF THE AGREED PAEDIATRIC INVESTIGATION PLAN

## A. CONDITION(S) / DISEASE(S)

Parenteral nutrition

## B. WAIVER

Not applicable.

## C. PAEDIATRIC INVESTIGATION PLAN

- **Condition to be investigated**

  Parenteral nutrition

- **Subset(s) covered**

  Preterm newborn infants, term newborn infants, infants & toddlers, children and adolescents from 0 to less than 18 years.

- **Formulation(s)**

  Solution for infusion

- **Studies / Measures**

| Area | Subarea | Number | Description |
|---|---|---|---|
| Clinical | safety | 1 | Prospective, open-label, multicentre, non-comparative safety study of "Paediatric Triple Chamber Bag" solution administered intravenously in children from 0 to less than 18 years requiring parenteral nutrition. |

| | |
|---|---|
| **Measures to address long term follow-up of potential safety issues in relation to paediatric use:** | **No** |
| **Date of completion of the paediatric investigation plan:** | **By December 2008** |
| **Deferral for some or all studies contained in the paediatric investigation plan:** | **No** |